REMARKS

The Amendments

Claims 1, 14 and 15 are amended to incorporate the substance, in part, of claim 3. Claims 2 and 3 are accordingly canceled. Claim 6 is amended to correct a minor grammatical error.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which may have been canceled by any of the above amendments.

The Rejections Rendered Moot

The rejections under 35 U.S.C. §103 of claims 1-2 and 6-12 over Hauel (AU 9210707) in view of Berstein (US Pub. No. 2003/0220297) and Doi (US Pub. No. 2004/0058914), of claims 1 and 13 over Hauel in view of Berstein and Doi further in view of Gaviraghi WO 00/27397), and of claims 1 and 14-15 over Ambuhl (US Pub. No. 2004/0198645) in view of Hauel, Berstein and Weinen (*Cardiovascular Drug Reviews*), are rendered moot by the above claim amendments. These rejections were not applied to claim 3 and the substance of claim 3 is now incorporated into claim 1 such that any rejection not applicable to claim 3 previously would not be applicable to amended claim 1 (nor any of the other claims, which all ultimately depend on claim 1).

The Remaining Rejection under 35 U.S.C. §103

The rejection of claims 1 and 3 under 35 U.S.C. §103 as being obvious over Hauel (AU 9210707) in view of Berstein (US Pub. No. 2003/0220297) and Doi (US Pub. No. 2004/0058914), further in view of Palomo (U.S. Patent No. 5,232,706) and Weinen (*Cardiovascular Drug Reviews*) is respectfully traversed.

The reasoning for the rejection is that Hauel in view of Berstein and Doi make obvious the compositions, as claimed, where the basic agent is lysine and that further in view of Palomo and Weinen it would have been obvious to exchange the lysine with arginine as the basic agent. Such reasoning, however, does not render the currently claimed invention obvious to one of ordinary skill in the art. The current claims recite that the basic agent,

selected from NaOH, KOH, $NaHCO_3$, $KHCO_3$, Na_2CO_3, K_2CO_3, Na_2HPO_4, K_2HPO_4 or meglumine. The combined teachings of the references fail to suggest a composition, as claimed, containing one these particular basic agents. For this reason, at least, the rejection under 35 U.S.C. §103 should be withdrawn. However, the following additional comments are provided.

Hauel discloses compounds of its generic formula (I) (page 1) which encompasses telmisartan. Telmisartan is specifically identified, e.g., in claim 6, as pointed out in the Office action. Hauel also discloses compositions containing telmisartan, see page 53, generally, and specific Examples I-VII at pages 113-118. Hauel does not disclose, even generally, to include a basic agent component or a poloxamer component in its compositions. Examples IV and V contain lysine, which is a basic agent, but Hauel does not suggest to use any other basic agent or basic agents, in general.

Berstein discloses the new family of compounds of its general formula (I). The compounds have a unique structure with a large ring; see paragraph 0010. Berstein teaches that these compounds may be administered with another active which can be selected from any of a large number of other actives, including telmisartan; see, e.g., paragraphs 0121 and 0224. Berstein teaches (e.g., at paragraph 0285) that any of a large variety of additional components may be used in its compositions with the unique compounds of formula (I).

Doi teaches compositions contain a NK-1 receptor antagonist of its formula (I) and an NK-2 receptor antagonist (see paragraphs 0002 and 0010 and paragraphs 0013-0022). The compositions are taught to treat a varied list of conditions related to tachykinin receptor antagonist activity, particularly urinary incontinence; see, e.g, pages 20-21, para. 0395. Doi discloses a wide variety of possible additional additives to its compositions depending on the various forms of administration chosen; see, e.g., pages 21-26, paras. 0398-0480.

Applicants urge, as an additional basis for overcoming the obviousness rejection, that the combined reference teachings fail to give one of ordinary skill in the art a reason to substitute the polyvinylpyrrolidone or other excipient component of Hauel with a poloxamer. The rejection is based, in part, on the allegation that the references, Berstein and Doi, give reason for one of ordinary skill in the art to exchange polyvinylpyrrolidone (povidone) and Pluronic® F68 (poloxamer 188) as binders for solid pharmaceutical dosage forms. Applicants respectfully submit that the references of record only teach the selection of polyvinylpyrrolidone (povidone) and Pluronic® F68 (poloxamer 188) as possible binders –

among others – for the particular compositions taught by either Berstein or Doi. These references do not teach that these components would be useful as binders for any pharmaceutical composition. Further, Doi indicates a preference for polyvinylpyrrolidone (povidone) for its compositions and no preference to Pluronic® F68 (poloxamer 188). Thus, Doi, even for its particular application, does not teach them to be equivalent because it indicates that polyvinylpyrrolidone (povidone) is preferred, presumably meaning it has some different and advantageous property compared to Pluronic® F68 (poloxamer 188). However, even if Berstein/Doi did teach them to be equivalent for the specific uses set forth therein, this would not suggest to one of ordinary skill in the art that they would be equivalent and interchangeable in the Hauel compositions. The Berstein and Doi compositions relate to very distinct compounds from those in Hauel and the compositions have distinct properties and distinct uses. The reference teachings do not provide one of ordinary skill in the art a reasonable expectation that the binders indicated for the specific use of Berstein or Doi would have the same or similar use in the Hauel compositions. Further, the disclosure in Doi relied on regarding the polyvinylpyrrolidone (povidone) and Pluronic® F68 (poloxamer 188) binders only applies to a very specific embodiment of Doi, i.e., compositions with the active in a solid core which is coated by a film-forming agent. In the other embodiments of Doi, the indication of useful binders or carriers includes polyvinylpyrrolidone (povidone) but not Pluronic® F68 (poloxamer 188) or other poloxamers; see, e.g., page 21, para. 0402; and, page 25, para. 0471. Thus, further indicating that they are not equivalent. For this additional reason, Berstein and Doi do not provide a reasonable expectation that the binders indicated for their specific compositions would have the same or similar use in the Hauel compositions.

Palomo discloses a specific manner of formulation of the specific drug omeprazol. The omeprazol is provided in a particular coated core structure with a basic compound. Palomo discloses certain specific basic compounds for this use which are certain salts of certain amino acids, including lysine and arginine. It is alleged in the Office action that Palomo teach lysine and arginine as basic compounds in a pharmaceutical formulation. Applicants submit that this teaching is being applied in an unsupported general manner. Palomo only teaches the applicability of lysine or arginine as a basic compound for compositions specifically containing omeprazole in a specific coated core structure. Palomo would not give one of ordinary skill in the art a reason to exchange arginine for lysine in any composition, particularly not in a composition such as Hauel directed to an unrelated active

compound. Additionally, as pointed out above, replacing lysine with arginine in the Hauel compositions will not meet or suggest the basic agent component of the current claims.

The Office action alleges that Wienen teaches that telmisartan is more soluble in a basic environment (referring to page 128, paragraph 4). This is not exactly what Wienen teaches however. Wienen teaches that the maximum solubility of telmisartan is at high and low pH and that it is poorly soluble in the mid-pH range of 3-9. Wienen does not include a basic agent with telmisartan in any of the experiments conducted there. Applicants see no basis for the allegation in the Office action that Wienen suggests including a basic agent in telmisartan compositions. Certainly, it provides no suggestion to combine a specific basic agent selected from NaOH, KOH, $NaHCO_3$, $KHCO_3$, Na_2CO_3, K_2CO_3, Na_2HPO_4, K_2HPO_4 or meglumine with telmisartan.

For all of the above reasons, it is urged that the combined teachings of the cited references, considered as a whole, fail to "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" see, e.g., KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, at 1396 (2007). Thus, the references considered as a whole fail to render the claimed invention obvious to one of ordinary skill in the art and the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,
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